

3. Plaintiff's claims are barred, in whole or in part, because there was no defect in the subject product at the time it left the manufacturer, seller and/or distributor's possession. The product was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was properly designed, manufactured, tested, inspected, and distributed with adequate and sufficient warnings at the time it left Merit's custody and control if, in fact, the product was manufactured or sold by Merit.

4. The injuries alleged by Plaintiff were or may have been caused, in whole or in part, by the misuse of the products, or because the use was contrary to the instructions provided with the products.

5. Plaintiff's claims are barred, in whole or in part, because at all times relevant the products and marketing of the products complied with all applicable laws and regulations to which the products were in any respect subject, including those of the U.S. Food and Drug Administration.

6. Plaintiff's claims are barred, in whole or in part, because the methods, standards, and techniques utilized in the preparation, design, manufacture, and marketing of the products were and are in conformity with the generally recognized state of medical knowledge, common and accepted procedure in the medical field, and state of the art at the time.

7. Plaintiff's claims are barred, in whole or in part, because the social utility and benefit of the products outweighed their risks, if any.

8. Plaintiff's claims are barred, in whole or in part, under Comment k of Section 402A of the Restatement (Second) of Torts (1965) and the Restatement (Third) of Torts: Product Liability §§ 2, 4, 6 and applicable case law.

9. Plaintiff's claims are barred, in whole or in part, by the principles set forth in Comment n to Section 388 of the Restatement (Second) of Torts (1965).

10. At all relevant times, the products at issue were accompanied by proper instructions for use, pursuant to generally recognized prevailing standards in existence at the time. The warnings and instructions on the products were not the proximate cause of any injury alleged by Plaintiff.

11. Any alleged product defect or negligence was not the proximate cause of the injuries alleged by Plaintiff.

12. Plaintiff's claims may be barred, in whole or in part, because Merit acted reasonably and in good faith.

13. Plaintiff's claims may be barred, in whole or in part, because Plaintiff did not reasonably rely on any representation or omission by Merit.

14. Plaintiff's claims may be preempted, in whole or in part, by federal law, including but not limited to the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321-394, the Supremacy Clause of the U.S. Constitution, and the general doctrine of federal preemption (express or implied).

15. Plaintiff's claims may be barred, in whole or in part, because the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321-394 do not provide for a private right of action.

16. Any injuries or damages that Plaintiff may have sustained were the result of Plaintiff's knowing and voluntary assumption of the medical risks associated with the use of the device described in the Complaint. Therefore, Plaintiff's damages are barred, in whole or in part, by the principles of comparative fault and/or assumption of risk and informed consent.

17. In the event that Plaintiff has sustained damages, as alleged in Plaintiff's Complaint, discovery or investigation may reveal that such injuries and/or damages were the result of the culpable conduct of Plaintiff, or another party or non-party. Should it be found, however, that Merit is liable to Plaintiff, any liability being specifically denied, then any damages are to be apportioned among the Plaintiff, co-Defendant and third-parties according to the degree of responsibility that each is found to have for the occurrence, in proportion to the entire measure of responsibility for the occurrence.

18. Plaintiff's claims are barred, in whole or in part, because the injuries alleged by Plaintiff may have been caused, in whole or in part, by pre-existing medical conditions unrelated to the allegations set forth in the Complaint and/or may have occurred by operation of nature or as a result of circumstances over which Merit had, and continues to have, no control.

19. Any damages that Plaintiff may have sustained were, or may have been, proximately caused by the negligence and fault of Plaintiff, and/or by the actions or inactions of third persons or parties or entities over whom Merit exercised no authority or control.

20. Plaintiff's damages, if any, were the result of intervening or superseding events, factors, occurrences, or conditions for which Merit is not liable.

21. Plaintiff's claims may be barred, in whole or in part, because Plaintiff failed to mitigate her alleged damages and failed to exercise reasonable care for her own health and safety.

22. Plaintiff's claims may be barred, in whole or in part, by the applicable statutes of limitation and repose.

23. Plaintiff's claims may be barred, reduced, and/or limited pursuant to

applicable statutory and common law regarding limitation of awards, caps on recovery, and setoffs. Specifically, Merit relies upon *Tenn. Code Ann. §29-39-102* to limit non-economic damages, if any.

PARTIES

1. Answering Paragraph 1, Merit is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of same is demanded.

2. Answering Paragraph 2, Merit admits that it is a Utah corporation, with its principal place of business at 1600 W. Merit Parkway, South Jordan, Utah, which manufactures and sells medical devices and products to hospitals and other health care providers throughout the United States and other countries. Merit admits the remaining allegations of this paragraph.

3. Answering Paragraph 3, Merit has insufficient information to form a belief as to the allegations of this paragraph and, therefore, neither admits nor denies the same.

4. Answering Paragraph 4, Merit has insufficient information to form a belief as to the allegations of this paragraph and, therefore, neither admits nor denies the same.

5. Answering Paragraph 5, Merit admits that Defendant Herbert Slatery (hereafter “Attorney General”) is a citizen and resident of the State of Tennessee who serves as Attorney General and Reporter for the State of Tennessee, and may be served with process at 425 5th Ave. N., Suite 2, Nashville, Tennessee 37243. Further, Merit admits upon information and belief, that the Attorney General was not negligent or otherwise involved in the treatment of the Plaintiff. The remaining allegations set forth a legal conclusion that does not require a response from Merit.

6. Answering Paragraph 6, Merit admits that it may be referred to as a “Defendant.”

7. Answering Paragraph 7, Merit is without sufficient information to admit or deny the

averments of this paragraph at this time. Merit's investigation is ongoing.

JURISDICTION AND VENUE

8. Answering Paragraph 8, Merit does not dispute jurisdiction of the United States District Court, Eastern District of Tennessee. Merit admits that it marketed its medical devices in Tennessee consistent with federal laws and regulations. However, Merit has insufficient information to admit or deny that it sold or shipped the specific device that was surgically implanted into the Plaintiff. The remaining allegation of Paragraph 9 is a legal conclusion that does not require a response from Merit.

9. Answering Paragraph 9, the allegation sets forth a legal conclusion that does not require a response from Merit.

10. Answering Paragraph 10, Merit admits that venue is proper in this district of federal court. Merit asserts that this is a civil action between citizens of different states, the amount in controversy exceeds the sum of \$75,000 (exclusive of interest and costs), and the Defendants, with the exception of the Attorney General, are not citizens of the State of Tennessee. The United States District Court for the Eastern District of Tennessee has original jurisdiction over this case pursuant to 28 U.S.C. § 1332 and removal is proper pursuant to 28 U.S.C. § 1441(a)-(b). Furthermore, Merit is without sufficient knowledge or information to form a belief as to whether the cause of action arose in Washington County.

FACTS

11. Answering Paragraph 11, Merit has insufficient information to admit or deny the averments of this paragraph at this time. Merit admits that during the time CryoLife manufactured a HeRO product line, at least one of its purposes was to provide improved vascular access for patients needing hemodialysis. The remaining allegation is admitted as stated.

12. Answering Paragraph 12, Merit admits these averments.

13. Answering Paragraph 13, Merit admits that the device is fully subcutaneous and admits that the quoted language is a small portion of a statement by Merit concerning the product.

14. Answering Paragraph 14, Merit denies that the HeRO graft is a relatively simple device. As to the remaining allegations, Merit is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations as this pertains to the specific product in question.

15. Answering Paragraph 15, Merit denies the allegation contained in the first sentence. Merit admits that the quoted language is a small portion of the statements by Merit concerning the product.

16. Answering Paragraph 16, Merit has insufficient information as to the averments of this paragraph and therefore neither admits nor denies the same.

17. Answering Paragraph 17, Merit admits that it did not seek PMA approval. Merit asserts that the regulatory pathway for medical devices is made by the FDA. Furthermore, Merit asserts that the device had already been cleared under the 510(K) process when Cryolife acquired Hemosphere. Merit asserts that the FDA did not require Merit to file a premarket approval application. Merit is without sufficient knowledge or information to form a belief as to the truthfulness of the remaining allegation therein.

18. Answering Paragraph 18, Merit denies the legal conclusion therein. Merit asserts that Federal law preempts the product liability laws of the State of Tennessee in this action.

19. Answering Paragraph 19, Merit admits that it has marketed the HeRO graft to general surgeons and vascular surgeons in the State of Tennessee during the time it owned the product line, and that such learned intermediaries were required to comply with the product's instructions

for use, which contained appropriate and federally approved risk information. Merit denies that it marketed the HeRO graft and other devices directly to consumer patients, including those living in Tennessee.

20. Answering Paragraph 20, Merit is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of the same is demanded.

21. Answering Paragraph 21, Merit is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of the same is demanded.

22. Answering Paragraph 22, Merit is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of the same is demanded.

23. Answering Paragraph 23, Merit is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of the same is demanded.

24. Answering Paragraph 24, Merit is without sufficient knowledge or information relative to the discussion between Plaintiff and her physician; however Merit asserts that the instructions for use provided with each HeRo graft device included the risk that the HeRO graft was subject to failure after implantation. Merit denies that no warnings were provided to Dr. Evans that the HeRO graft was subject to failure.

25. Answering Paragraph 25, Merit is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of the same is demanded.

26. Answering Paragraph 26, Merit denies the HeRO graft was unreasonably dangerous at the time that it left the control of Merit, if in fact it was marketed, manufactured or sold by Merit, and affirmatively alleges that the HeRO graft was federally approved for medical use consistent with its labeling. Furthermore, Merit denies that the device was dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased it.

27. Answering Paragraph 27, the allegations contained therein are denied as stated. Merit asserts that the device as manufactured does not tear in half within weeks of implantation and does not cause extensive blood clots in the lungs of the recipients.

28. Answering Paragraph 28, Merit is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of the same is demanded.

29. Answering Paragraph 29, Merit is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of the same is demanded.

30. Answering Paragraph 30, Merit is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of the same is demanded.

31. Answering Paragraph 31, Merit is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of the same is demanded.

32. Answering Paragraph 32, Merit is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of the same is demanded.

33. Answering Paragraph 33, Merit is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of the same is demanded.

34. Answering Paragraph 34, Merit is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of the same is demanded.

35. Answering Paragraph 35, Merit is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of the same is demanded.

36. Answering Paragraph 36, Merit is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of the same is demanded.

37. Answering Paragraph 37, Merit is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of the same is demanded.

38. Answering Paragraph 38, Merit is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of the same is demanded.

39. Answering Paragraph 39, Merit is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of the same is demanded.

40. Answering Paragraph 40, Merit is without sufficient knowledge or information to

form a belief as to the truthfulness of the allegations contained therein, and strict proof of the same is demanded.

41. Answering Paragraph 41, the allegations therein are denied.

COUNT I – STRICT LIABILITY

42. Answering Paragraph 42, Merit reasserts and incorporates by reference its responses herein to the allegations contained in Paragraphs 1 through 41 of the Complaint.

43. Answering Paragraph 43, Merit is without sufficient knowledge or information to form a belief as to whether it manufactured the device that is the subject of this action, and therefore denies the allegation.

44. Answering Paragraph 44, the allegations as stated are denied.

45. Answering Paragraph 45, the allegations as stated are denied.

46. Answering Paragraph 46, the allegations as stated are denied.

47. Answering Paragraph 47, the allegations as stated are denied.

48. Answering Paragraph 48, the allegations as stated are denied.

49. Answering Paragraph 49, the allegations as stated are denied.

50. Answering Paragraph 50, the allegations as stated are denied.

COUNT II – FAILURE TO WARN

51. Answering Paragraph 51, Merit reasserts and incorporates by reference its responses herein to the allegations contained in Paragraphs 1 through 41 of the Complaint.

52. Answering Paragraph 52, the allegations set forth a legal conclusion that Merit denies.

53. Answering Paragraph 53, the allegations contained therein are denied. Merit asserts

that, at a minimum, the requisite warnings appeared in the instructions for use. Furthermore, a trained medical professional would have knowledge of the risks associated with the HeRo graft device.

54. Answering Paragraph 54, the allegation contained therein is denied.

COUNT III – NEGLIGENCE IN DESIGN OR MANUFACTURE

55. Answering Paragraph 55, Merit reasserts and incorporates by reference its responses herein to the allegations contained in Paragraphs 1 through 41 of the Complaint.

56. Answering Paragraph 56, the allegation sets forth a legal conclusion that does not require a response from Merit.

57. Answering Paragraph 57, the allegations contained therein are denied.

58. Answering Paragraph 58, the allegations contained therein are denied.

59. Answering Paragraph 59, the allegations contained therein are denied.

COUNT IV – DECLARATORY JUDGMENT

60. Answering Paragraph 60, the allegation therein does not require a response from Merit; therefore, it is neither admitted nor denied.

61. Answering Paragraph 61, Merit admits that Plaintiff seeks a declaratory judgment that the provisions of Tenn. Code Ann. § 29-39-102 is unconstitutional, but Merit denies that Plaintiff is entitled to such relief.

62. Answering Paragraph 62, the allegations as stated are legal conclusions that Merit denies.

63. Answering Paragraph 63, the allegations as stated are legal conclusions that Merit denies.

64. Answering Paragraph 64, the allegations as stated are legal conclusions that Merit denies.

65. Answering Paragraph 65, the allegations as stated are legal conclusions that Merit denies.

66. Answering Paragraph 66, the allegations as stated are legal conclusions that Merit denies.

RESERVATION OF RIGHT TO NAME OTHER PERSONS

67. Answering Paragraph 67, Merit is without sufficient knowledge or belief to form a belief as to the cause of the personal injuries suffered by Plaintiff, but denies it is liable for Plaintiff's injuries.

JURY DEMAND

68. Answering the Jury Demand, Merit also requests a trial by jury of the maximum number of jurors permitted.

69. In answering the Prayer for Relief, Merit denies any and all liability to Plaintiffs.

70. All allegations in the complaint, not hereinabove expressly admitted or denied are now denied.

JURY DEMAND AND PRAYER FOR RELIEF

WHEREFORE, having fully answered and defended, Merit requests a trial by jury of twelve jurors on all issues and causes of action so triable in this cause, and prays for judgment as follows:

- A. That Plaintiff take nothing by the Complaint;
- B. That judgment be entered for Merit and against Plaintiff on each and every claim set forth in Plaintiff's Complaint;

- C. That Merit recover its fees, costs, and attorneys' fees incurred herein; and
- D. Such other and further relief as the Court deems just and proper.

This 2nd day of January, 2018.

MERIT MEDICAL SYSTEMS, INC.

s/ William B. Jakes, III
William B. Jakes, III # 10247
HOWELL & FISHER, PLLC
300 James Robertson Parkway
Nashville, TN 37201-1107
(615) 244-3370
Attorney for Defendant
Merit Medical Systems, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on the 2nd day of January, 2018, a copy of the foregoing **Answer** was filed electronically using the Court's ECF system. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. All other parties will be served by regular U. S. Mail. Parties may access this filing through the Court's electronic filing system.

s/William B. Jakes, III
William B. Jakes, III